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FIRST NAMED INVENTOR ATTORNEY DOCKET NO. APPLICATION NO. FILING DATE BUSFIELD 02/14/00 49/503.387 **EXAMINER** HM12/1229 020543 STRZELECKA, I PENNIE AND EDMONDS 1155 AVENUE OF THE AMERICAS ART UNIT PAPER NUMBER MEW YORK NY 10036-2711 1656

DATE MAILED:

12/29/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

| <u> </u> | | Δnn | lication No. | | Applicant(s) | | |
|---|---|---|---|--|---|--------------|--|
| Office Action Summary | | | | • | | | |
| | | | 503,387 | | BUSFIELD ET AL. | | |
| | | | miner | | Art Unit | | |
| | | | sa E Strzele | | 1656 | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | | |
| THE - Exte after - If the - If NC - Failu - Any r | ORTENED STATUTORY PERIOD F MAILING DATE OF THIS COMMUN nsions of time may be available under the provisions SIX (6) MONTHS from the mailing date of this come period for reply specified above is less than thirty (6 period for reply is specified above, the maximum s tre to reply within the set or extended period for reply reply received by the Office later than three months and patent term adjustment. See 37 CFR 1.704(b). | IICATION. s of 37 CFR 1.136 (a). In munication. 30) days, a reply within ti atutory period will apply y will, by statute, cause t | n no event, howe he statutory mini and will expire S he application to | ever, may a reply be tim imum of thirty (30) days SIX (6) MONTHS from to become ABANDONED | nely filed s will be considered timely. the mailing date of this com 0 (35 U.S.C. & 133) | nmunication. | |
| 1) | Responsive to communication(s) f | iled on | | | | | |
| 2a) <u></u> □ | This action is FINAL . | 2b)⊡ This action | on is non-fir | nal. | | | |
| 3) | 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Dispositi | on of Claims | | | | | | |
| 4) Claim(s) 1-23 is/are pending in the application. | | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | | |
| 6) Claım(s) is/are rejected. | | | | | | | |
| 7) 🗌 | 7) Claim(s) is/are objected to. | | | | | | |
| 8)[] | 8) Claims 1-23 are subject to restriction and/or election requirement. | | | | | | |
| Applicati | on Papers | | | | | | |
| 9) The specification is objected to by the Examiner. | | | | | | | |
| 10) The drawing(s) filed on is/are objected to by the Examiner. | | | | | | | |
| 11) The proposed drawing correction filed on is: a) approved b) disapproved. | | | | | | | |
| 12) The oath or declaration is objected to by the Examiner. | | | | | | | |
| Priority u | ınder 35 U.S.C. § 119 | | | | | | |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d). | | | | | | | |
| a) ☐ All b) ☐ Some * c) ☐ None of | | | | | | | |
| u)L | | | | | | | |
| | 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| | | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | |
| 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e). | | | | | | | |
| Attachment(s) | | | | | | | |
| _ | ce of References Cited (PTO-892) | | 12\ | Interview Cummer | /DTO 442) Barrar N. / | | |
| 16) 🔲 Notic | ce of References Cited (PTO-692) ce of Draftsperson's Patent Drawing Review (mation Disclosure Statement(s) (PTO-1449) I | | 18) [19) [20) [| · | r (PTO-413) Paper No(s Patent Application (PTO | | |
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DETAILED ACTION

Election/Restrictions

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-7, 13, 19, drawn to polynucleotides, vectors, host cells and methods of making a polypeptide, classified in class 435, subclass 69.4, for example.
 - II. Claims 8-10, drawn to a polypeptide, classified in class 530, subclass 399, for example.
 - III. Claims 11-12, 16, drawn to an antibody to a polypeptide, classified in class 530, subclass 387.1, for example.
 - IV. Claims 14-15, drawn to a method of detecting the polypeptide, classified in class 436, subclass 501, for example.
 - V. Claims 17-18, drawn to a method of detecting DNA, classified in class 536, subclass 24.3, for example.
 - VI. Claims 20-21, drawn to a method of identifying a binding partner, classified in class 436, subclass 501, for example.
 - VII. Claim 22, drawn to a method of modulating an activity of a polypeptide, classified in class 435, subclass 4, for example.
 - VIII. Claim 23, drawn to a method of identifying a compound which modulates the activity of a polypeptide, class undeterminable, subclass undeterminable.
- 2. The inventions are distinct, each from the other because of the following reasons:
- 3. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of Group I could be used in an entirely different method, such as in a method of detection of the polynucleotide in a sample, rather than in a method of making the polypeptide.

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- 4. Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group II could be used for an entirely different purpose such as in the method of Group VIII, rather than for the production of antibodies of Group III.
- Inventions I-III are also unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to chemically different compounds which can be made and used without each other. Furthermore, the inventions of Groups I-III lack a common utility which is based upon a common special technical feature which is disclosed as being responsible for the common utility.
- 6. Inventions II and (VI-VIII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Group II could be used in an entirely different manner, such as in a method of making antibodies rather than in the methods of Groups VI-VIII.
- 7. Inventions (I and III) and (V-VIII) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one

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for the other in that the DNA and antibody of Groups I and III are not required for the methods of Group V-VIII.

- 8. Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies of Group III could be used in an entirely different manner, such as in the purification of the polypeptide rather than in the method of Group IV.
- 9. Inventions II and (IV-V) are unrelated, respectively. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not required one for the other in that polypeptide of Group II is not required for any of the methods of Groups IV-V.
- Inventions IV-VIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to methods which have different method steps, starting materials and goals.
- 11. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and the necessity for non-coextensive literature searches, restriction for examination purposes as indicated is proper.

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12. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E Strzelecka whose telephone number is (703) 306-5877. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

ts December 28, 2000

TS

KENNETH R. HORLICK PRIMARY EXAMINER GROUP 1800 (1000) 14 / 18/00

Plante P. Holding Ph. D.